(19) Europäisch s Patentamt
European Patent Offic
Office européen des brevets

(11) Publication number: **0 607 511 A2**

(12) EUROPEAN PATENT APPLICATION

(21) Application number: **93117897.4**

(22) Date of filing: **04.11.93**

(51) Int. Cl.[5]: **A61B 5/04**, A61B 5/0402, A61N 1/37

(30) Priority: **18.12.92 SE 9203822**

(43) Date of publication of application: **27.07.94 Bulletin 94/30**

(84) Designated Contracting States: **DE FR GB IT NL**

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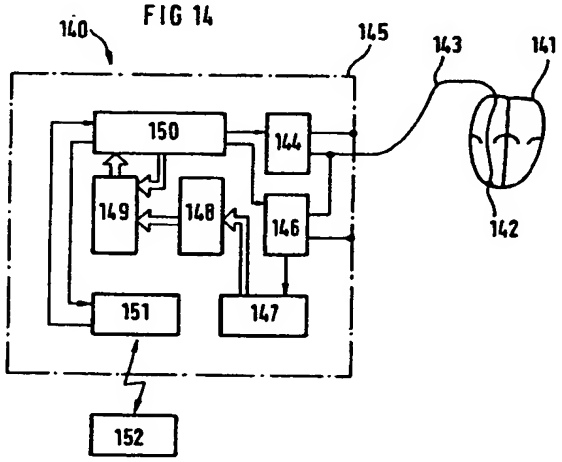
(54) Device for analyzing the function of a heart.

(57) A device (140) for analyzing the function of a heart, containing a measurement unit (146) for generating a first measurement signal related to a first electrical or mechanical heart variable and an evaluation unit (148, 149) for evaluating the measurement signal, is described. The device (140) further contains a means (147) for generating a parameter signal related to a heart variable, the evaluation unit (148, 149) analyzing the related values for the measurement signal and the parameter signal. The device (140) can be used for detecting a number of functional aberrations, such as bradycardia, tachyarrhythmia, retrograde conduction, ischemia and ectopia, and for controlling pacemakers and defibrillators.

FIG 14



EP 0 607 511 A2

The present invention relates to a device for analyzing the function of a heart, comprising a measurement unit for generating a first measurement signal related to a first electrical or mechanical heart variable, and an evaluation unit for evaluating the measurement signal.

In the monitoring, diagnosis and treatment of heart diseases or other changes in a heart, accurate determination of the heart's current condition, with minimal risk of erroneous interpretations, is important. Automatic monitoring of the heart is valuable so therapeutic measures can be instituted without delay when needed.

There are numerous heart variables, both electrical and mechanical, such as the electrocardiographic (ECG) signal, the heart's impedance, blood pressure, blood volume, blood flow, heart sounds and movements of the heart walls, which reflect the heart's function. The sensing of any of these variables to obtain a measurement signal which can be evaluated in establishing the condition of the heart is prior art.

One way to graphically elucidate the electrocardiogram by plotting the voltage of a recorded electrocardiogram against the time derivative of the voltage is described in an article entitled "Phase Plane Plot of Electrograms as a Marker of ventricular Electrical Instability During Acute Ischemia: Initial Experimental Results and Potential Clinical Applications", published in the journal PACE, Vol. 15, part II, November 1992, pp. 2188-2193. This procedure produces a curve equivalent to the recorded ECG signal. The article shows that there is a relationship between changes in parts of the curve during acute ischemia and development of ventricular fibrillation. The authors of the article feel that a presentation of an electrocardiogram in graphical form can be an excellent complement to traditional real-time presentation.

US-A-4,417,306 describes an apparatus which monitors and stores heart signals. The apparatus senses the ECG, and the ECG signal must have a predetermined slope, amplitude, duration and course to be accepted as a heart beat. The QRS complex is the main segment sensed, i.e. the electrical signals occurring in the heart when there is a ventricular beat (ventricular systole).

US-A-4,453,551 describes an apparatus designed to detect ventricular fibrillation (VF). The apparatus senses the ECG signal from the heart, digitizes it and amplifies it to a predetermined peak amplitude. The amplified signal can then be analyzed in different ways to ascertain whether or not VF is present. For example, the statistical distribution of gradients or the frequency of the maximum negative gradient can be analyzed.

EP-A-0 220 916 describes an apparatus designed to detect the presence of ventricular tachycardia (VT) and VF and to supply treatment terminating these conditions. The apparatus senses the heart's ECG at a plurality of points in the heart and determines the sequence in which the signals are detected at the different measurement points. In VT and VF, the detected sequence deviates from the normal sequence in different ways.

The object of the invention is to provide a device which analyzes the function of the heart in a safe, efficient but still simple manner.

Another object of the invention is to provide a device which can be used for diagnosing heart defects, monitoring heart functions and adapting therapy so treatment is as safe and effective as possible.

One such device is achieved in accordance with the present invention in that the device according to the preamble is devised so the evaluation unit further comprises a means for generating a parameter signal related to a heart variable, and the evaluation unit analyzes related values for the measurement signal and parameter signal.

Instead of analyzing a measurement signal with respect to its characteristics (amplitude, slope, duration), the device analyzes the related values of two signals, i.e. the measurement value and the parameter value are analyzed for the same points in times in the course of the heart variable. In principle, the related values correspond to coordinates in the plane established by the two signals whose changes over time can be analyzed for obtaining information on the condition of the heart. A normally working heart is hemodynamically stable, and related values repeat, in principle, from one heart cycle to another. When two conditions must be satisfied simultaneously (the measurement value and parameter value must both be repeated in the same way when heart function is normal), the possibility of accurately detecting both normal heart function and deviations from normal function increase. Different deviations produce characteristic changes in the signals and can therefore be identified with great accuracy. The measurement signal and parameter signal can be related to the same heart variable. For example, in a pacemaker a unipolar ECG signal can serve as the measurement signal while a bipolar ECG signal can serve as the parameter signal.

An improvement of the device is obtained in accordance with the invention in that the evaluation unit plots the first measurement signal against the parameter signal and analyzes the morphology and/or chronological course of the curve obtained.

A curve is obtained when the analysis is performed so the measurement signal is plotted against the parameter signal. As noted above, a heart is hemodynamically stable when working normally, and a virtually identical curve is generated

for each heart cycle, depending on the measurement signal and parameter signal selected. Pathological changes and other anomalies and conditions in the heart affect the shape of the curve in a distinct way and can therefore be easily identified.

It is an advantage here if the means for generating a parameter signal comprises a derivator which derives the measurement signal, the derived measurement signal then serving as the parameter signal.

This produces a curve related to only one measured heart variable. For example, a heart's impedance can be plotted against the derivative of that impedance, blood pressure plotted against the derivative of blood pressure or the heart's ECG signal plotted against the derivative of the ECG signal. In the first two instances, largely circulary shaped curves are obtained whose size depends on e.g. the heart rate. In the latter instance, a curve is obtained consisting of two closed loops per heart cycle at a normal heart rate.

Alternately, the device can be devised so the means for generating a parameter signal senses a second heart variable and generates a second measurement signal serving as the parameter signal.

The plotting of two signals, related to different measured heart variables, against one another, increases the number of possible combinations, and the most suitable curve for identifying a particular disorder, a particular pathological condition or some other change can be selected. For example, pressure can be plotted against impedance, producing a simple, largely closed curve corresponding to the heart's work in each heart cycle. Infarction can be demonstrated from this curve, since infarction affects the heart's work capacity.

Additional possibilities for identifying different phases of the heart are obtained in accordance with the invention in that the device comprises a further measurement unit for generating at least one further measurement signal related to at least one further heart variable, whereby the evaluation unit analyzes related values for the first measurement signal, the parameter signal and the further measurement signal.

This produces a multidimensional curve. In principle, any number of heart variables and derivatives of heart variables can be plotted against each other and analyzed. A three-dimensional curve is obtained if impedance is plotted against pressure and the ECG. For every heart cycle, this curve forms a simple closed curve which repeats one heart cycle after another in a healthy heart. An extra or premature ventricular systole would produce a major deviation in the curve. A hemodynamically instable tachyarrhythmia is also easily identified, since the curve is then not repeated in every heart cycle.

An improvement of the device is obtained in accordance with the invention in that a comparator unit continuously senses the related values in order to detect signal drifting by the related values, and a compensation unit compensates the current related values for any current signal drift.

Since heart signals generally display a cyclical course, various signal drifting can therefore be compensated for. For example, low-frequency, superimposed signals can thereby be eliminat d from the actual measurement signal. The device can easily normalize the signals, since they display high repeatability.

Another way of filtering the related values is obtained in accordaance with the invention in that, after a first measurement signal and a second measurement signal have been generated, a filter unit compares changes in the respectively related values to previously stored related values, and noise is identified if a noise change is found in one related value without any equivalent change being found in the second related value, and the noisy related value is compensated for the specific noise.

For example, ECG signals and impedance signal are affected by certain types of noise caused by e.g. patient breathing. However, one heart variable, such as blood pressure, is not affected by noise in the same way as purely electrical heart signals and can therefore be used for identifying noise in the electrical signals and vice-versa.

Yet another way of filtering a signal with the aid of the device is achieved in accordance with the invention in that a floating averager continuously calculates the average value for the respective related value over a predetermined previous period of time.

A plurality of advantageous embodiments of the device for analyzing related values is obtained according to the present invention, some of which will be described below in greater detail.

A first embodiment is obtained in that the evaluation unit comprises an arc length calculator which calculates the arc length of the curve, preferably for one heart cycle, the calculated arc length value then designating the condition of the heart's function.

For certain measurement signal-parameter signal pairs (e.g. impedance and the derivative of impedance), the arc length of the curve for every heart cycle corresponds to prevailing hemodynamic stability, making it easy to establish from the arc length whether or not the heart is beating at an innocuous rate or if the heart is displaying unstable bradycardia or tachyarrhythmia. If the change in arc length from one heart cycle to another is recorded, hemodynamic stability can be identified and employed as a sub-condition of the

rate in determining whether or not an unstable arrythmia is present. Rapid changes are indicative of abnormal events in the heart.

In this first embodiment, it is an advantage if the measurement unit measures impedance in the heart, the means for generating a parameter signal derives the impedance signal, an A/D converter digitizes the impedance signal and the impedance derivative signal, the arc length calculator calculates the arc length for each heart cycle of the curve to which the impedance signal and the impedance derivative signal correspond, a number of comparators respectively compares the calculated arc length to a predetermined arc length, the respective comparator then generating an output signal if the calculated arc length exceeds the respective predettermined arc length, and a microprocessor, using the output signals from the comparators, determines whether or not the heart is hemodynamically stable.

Different hearts vary in their ability to withstand high rates, and the most important thing is actually whether the heart is hemodynamically stable, i.e. that it pumps blood in a normal manner, so heart rate does not always constitute the best indicator of the condition of the heart. For example, some patients may have problems at a heart rate of 150 beats/min, whereas other patients might be able to withstand more than 200 beats/min without any impairment in the pumping capacity of their hearts. During the heart cycle, impedance changes in such a way that it rises during systole when blood is pumped out of the heart and falls during diastole when the heart fills with blood. The change in impedance is more rapid at the beginning of systole and the beginning of diastole respectively, as reflected in their derivative signals. In a coordinate system, impedance and impedance derivative signals form a closed curve for each heart cycle, and the arc length only varies within certain limits as long as the heart is hemodynamically stable. When the heart is no longer able to work in a hemodynamically stable fashion, the arc length declines, something easily detected by a comparator. Depending on the different output signals from the comparators, the heart's hemodynamic condition can therefore be continuously monitored. This would not be possible if e.g. only the heart rate or the peak-to-peak value for impedance, which do not vary as systematically as the arc length in the presence of hemodynamic instability, were considered.

A second embodiment is obtained in that the evaluation unit comprises an area calculator which calculates an area, largely enclosed by the curve, for every heart cycle, the calculated area then designating the condition of the heart's function.

Area is related to hemodynamic stability in the corresponding way as arc length for certain measurement signal-parameter signal pairs and can be used in the corresponding way as arc length for identifying unstable arrhythmias. For other measurement signal-parameter signal pairs (pressure and impedance or volume and pressure), area represents the work performed by the heart in each heart cycle, and this can be used for controlling an atrio-ventricular interval in a dual chamber pacemaker so optimum function is attained for the heart or for controlling the emission of stimulation pulses in a way which optimizes the heart's work.

A third embodiment is obtained in that the evaluation unit plots an essentially simple, closed curve and a distance calculator calculates the distance between specific points on the curve, preferably between maximum and minimum points, the calculated distances designating the condition of the heart's function.

In the corresponding way as for arc length and area, the distances between points on the curve for certain measurement signals and parameter signals represent the stability of the heart. The ratio between certain distances, such as the distance between the maximum and minimum points on the curve for the respective coordinate axis, can be established. Variations in the distance can be calculated and utilized for e.g. determining the heart's work. With e.g. blood pressure in the heart as a variable, conditions in which the heart's pumping capacity declines can be easily identified, since pressure changes during a heart cycle then decline.

A fourth embodiment is obtained om that the evaluation unit comprises a memory for storing the obtained curve for each heart cycle and a comparator for comparing the obtained curve with at least one predetermined curve, the predetermined curve being either a previously stored curve or programmed curve.

In this manner, the morphology of each heart cycle can be directly compared with morphologies in normal hearts and with pathological conditions or other anomalies. For example, mild infarctions sustained by the heart, extrasystoles and retrograde conduction can be detected.

A fifth embodiment is obtained in that the evaluation unit comprises a memory for storing the course of related values, and a comparator for comparing the stored course with at least one predetermined course, the predetermined course being either a previously stored course or a programmed course.

As previously noted, the related values follow a course which essentially repeats from one heart cycle to another. Different conditions can be identified if this course is monitored. The course can be

monitored e.g. by regarding related values as coordinates whose change over time produces the course, by calculating vectors derived from the related values or by calculating gradients from changes in related values. For example, distinctions can thereby be made between different forms of arrhythmias arising from different foci in heart tissue, and both old and new conditions suffered by the patient can also be detected. Different therapies can be provided, depending on the therapy previously found to be effective for the various arrhythmias.

In this context, it is an advantage if the device comprises a component for identifying a sequence with which the course of related values passes a predetermined number of areas and the comparator compares the sequence to a predetermined sequence, the predetermined sequence being either a previously identified sequence or a programmed sequence.

Since the related values repeat, sensing only certain areas traversed by the values and identifying that sequence, or possibly even the time interval between the different areas, is sufficient. Different arrhythmias follow different paths and can also be identified in the corresponding manner.

Such a device is specified in a simultaneously filed patent application with application number

The invention is described in greater detail in conjunction with 22 Figures, whereby

FIG. 1 shows a first embodiment of the device in accordance with the invention, used in an ECG apparatus;

FIG. 2 shows the first embodiment in form of a block diagram;

FIG. 3 illustrates in form of a diagram the function of the first embodiment;

FIG. 4 shows an ECG for one heart cycle:

FIG. 5 shows in form of a block diagram a second embodiment of the device, used in a pacemaker;

FIGS. 6-8 illustrate in form of diagrams the function of the second embodiment.

FIG. 9 shows in form of a block diagram a third embodiment of the device, used in a pacemaker;

FIGS. 10-11 illustrate in form of diagrams the function of the third embodiment;

FIG. 12 shows in form of a block diagram a fourth embodiment of the device, used in a pacemaker;

FIG. 13 shows the fourth embodiment in a more detailed block diagram;

FIG. 14 shows in form of a block diagram a fifth embodiment of the device, used in a rate-responsive pacemaker;

FIG. 15 shows how impedance in the heart varies during a heart cycle;

FIG. 16 illustrates in form of a diagram the function of the fifth embodiment.

FIG. 17 shows in form of a block diagram a sixth embodiment of the device, used in a rate-responsive pacemaker.

FIG. 18 illustrates in form of a diagram the function of the sixth embodiment.

FIG. 19 shows in form of a block diagram a seventh embodiment of the device, used as a noise filter;

FIG. 20 shows in form of a block diagram an eighth embodiment of the device, used as a noise filter.

FIG. 21 illustrates in form of a diagram the function of a ninth embodiment of the device, and

FIG. 22 shows in form of a block diagram a tenth embodiment of the device, used in a pacemaker.

FIG. 1 shows a patient 1 who is connected to the ECG recorder 2 via a first electrode 3 , a second electrode 4 and a third electrode 5 . The patient's 1 ECG signal may be sensed in a routine examination of the patient's health, for diagnosis of a suspected heart condition or for monitoring of the patient's 1 heart. A signal analysis device 6 is provided in the ECG recorder 2 to analyze the ECG signals picked up by the electrodes 3, 4, 5 .

FIG. 2 shows an embodiment of the signal analysis device 6. The ECG signal is fed into an amplifier 10 and then filtered in a bandpass filter 11 before the signal is transferred to a derivator 13 for derivation and to a buffer 12 in which it is chronologically synchronized with the derived signal. The signal in the buffer 12 and the derived signal are then transferred, via a first A/D converter 14 and a second A/D converter 15 respectively to a RAM 16 . Related values for the two input signal are stored in parallel in the RAM 16 . The related values are chronologically simultaneous signals. The digitized signals then pass from the RAM 16, via a data bus 17 , to a first subtractor 18 in which current measurement values are subtracted from a

basic signal. The basic signal can consist of a previously recorded and stored ECG signal from the same patient. Differences can be calculated for entire heart cycles or parts of heart cycles, mainly depending on the heart rate and noise frequencies. Difference values are then fed to an averager 19 which calculates an average value for the difference. The difference is also fed to a signal buffer 20 for subsequent use as a diagnostic aid. The averaged signal is sent to a second subtractor 21 to which the original signal is also sent in order to compensate it for noise in the recorded ECG signal. From the second subtractor 21 the signal passes a first D/A converter 22 , and the difference signal is fed to a second D/A converter 23 from the signal buffer 20 . Both signals are now fed to a recording unit 24 which can consist of a recorder, monitor or the like.

The ECG signal before and after signal conditioning is illustrated in FIG. 3 in which the recorded ECG signal is designated 30 . The recorded ECG signal 30 has a superimposed noise signal with a lower frequency, making interpretation of heart signals more difficult. In the signal analysis device 6, as described in FIG. 2, the ECG recorded signal 30 is normalized in relation to a previously stored, correct ECG signal, and the ECG signal is compensated for the distortion caused by signal noise by subtraction of the noise from that ECG signal 30 . The conditioned ECG signal, designated 31 , is much more distinct and much easier for the physician to interpret. In principle, the difference signal 32 produced in the signal analyzer reflects the noise. Noise can be caused by e.g. the patient's 1 breathing. So the difference signal 32 can also be used for recording the patient's 1 breathing. Deviations in the recorded ECG signal 30 in relation to the stored basic signal also appear in the difference signal. These changes may be due to changes in the heart, such as infarction, ischemia or late potentials.

The morphology of a heart signal is shown in FIG. 4 and generally designated 33 . The heart signal 33 consists of a P wave caused by atrial depolarization (which starts atrial systole), a QRS wave caused by ventricular depolarization (which starts ventricular systole) and a T wave caused by ventricular repolarization. Pathological and other changes in the heart affect the heart signal 33 in characteristic ways. Elevation 34 of the signal in the S wave and the T wave is generally caused by infarction in the heart, said infarction impairing the heart's work capacity. On the other hand, depression 35 of the signal between the S wave and the T wave is generally caused by ischemia, i.e. inadequate blood perfusion in local areas of the heart, leading to hypoxia in the heart. One of the most common causes of cardiac ischemia is arteriosclerosis. Changes at the end of the T wave, here designated 36a, 36b in the heart signal 33, are generally interpreted as changes increasing the risk of tachycardia or fibrillation, compared to other hearts. So such a change may be a sign that the patient needs treatment with medication or an implantable defibrillator.

FIG. 5 shows an implantable dual chamber pacemaker 40 which is connected to a heart 41 to sense the heart's ECG and deliver treatment when necessary. The pacemaker 40 is connected to the heart 41 with a first tip electrode 42 and a first ring electrode 43 . The first tip electrode 42 and the first ring electrode 43 are connected, via a first electrode conductor 44 and a second electrode conductor 45 , to an atrial pulse generator 46 . An atrial detector 47 is connected in parallel across the pulse generator 46 to sense the heart's 41 ECG signal.

In the corresponding manner, a second tip electrode 48 and a second ring electrode 49 are connected, via a third electrode conductor 50 and a fourth electrode conductor 51 , to a ventricular pulse generator 52 . A ventricular detector 53 is connected across the ventricular pulse generator 52 to sense the heart's 41 ECG signal. The pulse generators 46, 52 and the detectors 47, 53 are controlled by a control device 54 .

The ECG signals picked up by the detectors 47, 53 are fed to a signal conditioning unit 55 in the control device 54 . The input signals are processed in the signal conditioning unit 55 in the same was as shown in FIG. 2, i.e. with gain, filtration, buffering and derivation respectively and A/D conversion. The digitized signals are transferred to a RAM 56 which sequentially stores the related values. In principle, stored values correspond to coordinates in a coordinate system which has the ECG signal as one axis and the derived ECG signal as the other axis. The stored related values form a curve in this coordinate system. The related values are sent from the RAM 56 to an area analyzer 57 . The area analyzer 57 senses whether the related values pass specific areas in the coordinate system. Information on the areas passed and the sequence in which they are passed is transferred to a sequence identifier 58 which compares the sequence with previously stored or programmed sequences. Sequence information is sent from the sequence identifier 58 to a control unit 59 . On the basis of this transmitted information, the control unit 59 decides whether or not therapy should be instituted. If the sensed sequence of related values results in a sequence which is not stored in the sequence identifier 58 , this sequence is sent from the RAM 56 to an extra memory 60 . From there it can then be retrieved and studied by a physician.

To permit the pacemaker 40 to transmit information on new sequences or accept programming, the pacemaker 40 is equipped with a telemetry unit 61 connected to the control unit 59. The telemetry unit 61 can telemetrically transmit information between the control unit 59 and an extracorporeal programming unit 62 .

The analysis of the ECG signal which takes place in the pacemaker 40 is illustrated in greater detail in FIGS. 6 to 8 which show different heart signals in a coordinate system with the ECG signal and the derivative of the ECG signal as axes. Five analysis areas 70a -e are designated in the three FIGS. 6 to 8. Fig. 6 shows a curve 71 for a normal heart beat. It traverses all five analysis areas 70a - e in a specific sequence and can therefore be easily identified as a natural event by the pacemaker 40 . FIG. 7 shows a tachyarrhythmia curve 72 at about 150 pulses/minute. The tachyarrhythmia curve 72 only passes three analysis areas 70b, 70d, 70c and is therefore very easy to identify. A tachyarrhythmia can originate at various foci in heart tissue, and every specific type of tachyarrhythmia can be identified in this way according to the sequence in which the curve passes the analysis areas 70a - e . This is particularly important, since the most effective termination of different tachyarrhythmias can demand different therapeutic stimulation sequences. In addition, certain tachyarrhythmias are hemodynamically stable, i.e. do not require any therapeutic intervention, whereas other tachyarrhythmias spontaneously subside after a time and do not require any treatment either. In the case of unstable tachyarrhythmias, the control unit 59 can be programmed with a plurality of different therapeutic pulse rates and, depending on the tachyarrhythmia detected, deliver the therapeutic measure which has proved to be most effective for that type of tachyarrhythmia. FIG. 8 illustrates a heart fibrillation 73 which only gives rise to a small, simple, closed ring which passes two analysis areas 70c, 70d in this instance. Defibrillation of the heart 41 can be necessary when fibrillation occurs. An implantable defibrillator could then include the pacemaker functions.

FIG. 9 shows an alternative embodiment of the device according to the invention. A signal analyzer 80 amplifies an ECG signal in an amplifier 80 and filters it in a bandpass filter 82 before the signal is fed to a buffer 83 and to a derivator 84 in which it is derived.

The buffered signal and the derived signal are digitized in a first A/D converter 85 and the second A/D converter 86 respectively and fed to a cyclical RAM 87 . Since both the ECG signal and its derivative is used, simple signal normalization can be performed in the cyclical RAM 87 .

The signals are then fed to a polarity detector 88 which senses whether the derived signal is positive or negative. For each heart cycle, a sequence of changes in the derivative during the heart cycle is sent to a morphology comparator 89 . The morphology comparator 89 compares this sequence with previously generated sequences and identifies the current condition of the heart, e.g. whether or not it is functioning normally, whether it is responding to stimulation pulses, whether it is in arrhythmia etc.

Two different heart rhythms are illustrated in FIGS. 10 and 11. A first ECG-ECG derivative tracing 95 is drawn in FIG. 10. This first tracing 95 has a typical, readily identifiable sequence of alternating positive and negative derivatives whose respective arc lengths can be obtained e.g. in the form of a number of sampled values with positive or negative derivatives. A second ECG-ECG derivative tracing 96 , shown in FIG. 11, has a different sequence of positive and negative derivatives with other arc lengths under the positive and negative segments respectively. In the individual patient, every heart condition (normal function, stable tachyarrhythmia, unstable tachyarrhythmia, fibrillation etc.) has a characteristic, recurrent sequence of positive and negative derivatives with specific arc lengths. The signal analyzer 80 can be programmed to learn the different sequences occurring in a patient and storing same for retrieval by a physician who can then get a good picture of the heart's condition and function.

Another criterion which can be employed in improving reliability in the identification of a specific condition is the ECG signal itself (positive, negative, arc length).

As noted above, it is easy for the signal analyzer 80 to normalize the signal which, in contrast to analyzers which only examine the derivative signal, results in easy attainment of a zero level for the derivative on a stable level, i.e. conditioning of the ECG derivative signal readily compensates for signal drifting, making the analysis more reliable.

FIG. 12 shows a single chamber pacemaker 100 which is connected to a heart 101 . A tip electrode 102 and a ring electrode 103 are placed in the ventricle of the heart 101 and connected, via a first electrode conductor 104 and a second electrode conductor 105 , to a pulse generator 106 in the pacemaker 100 . A detector electrode 107 is connected to the exterior of the heart near the tip electrode 102 and, via a third electrode conductor 108 , to a detector 109 in the pacemaker 100 . The detector 109 is also connected to the first electrode conductor 104 . The detector 109 senses the impedance of the heart wall between the tip electrode 102 and the detector electrode 107 and transfers this signal to a signal analysis device 110 which is

described in greater detail in FIG. 13. Results of the signal analysis are sent to a control device 111 which, according to the impedance signal analyzed by the signal analysis device 110, controls the pulse generator 106 .

Like previously described pacemakers, this pacemaker contains a telemetry unit 112 which transmits information between the control device and an extracorporeal programming unit 113 .

In the signal analysis device 110, as shown in FIG. 13, the impedance signal first passes an amplifier 120 and a bandpass filter 121 before the signal is split into two parts. The first part goes to a buffer 122 and the second part goes to a derivator 123 . From the buffer 122 and the derivator 123 the signals are respectively multiplexed in a multiplexer 124, fed to an A/D converter 125 and then stored in a RAM 126 . From the RAM 126 the related values are sent to a arc length calculator 127 which calculates the arc length of the curve which impedance and the derivative of impedance form in a coordinate system with impedance and the derivative of impedance as coordinate axes. The arc length calculator 127 suitably calculates the arc length for every individual heart cycle. The measured arc length is then transferred to a first comparator 128 , a second comparator 129 , a third comparator 130 and a fourth comparator 131 for comparison to previously stored or programmed arc lengths. The values to be compared to the current arc length are transferred from the control device 111 via a first signal conductor 132 , a second signal conductor 133 , a third signal conductor 134 and a fourth signal conductor 135 . The comparators 128, 129, 130, 131 are devised to emit a signal only if the current measured arc length exceeds the arc length to which it is compared. The control device 111 even utilizes the time interval between the signals from comparators 128-131 as a subcondition in the analysis. This means that the output signal from the four comparators 128, 129, 130, 131 which are transferred to the control device 111 can designate five different arc length intervals which, with the time intervals, can be analyzed by the control device 111 . The first occurs when the current arc length is shorter than all the arc lengths to which it is compared. The output signal from the comparators 128-131 is then zero which means that the heart has a hemodynamically unstable tachyarrhythmia when the time interval is short and hemodynamically unstable bradycardia when the time interval is long. The second situation occurs when the current arc length is only longer than one of the arc lengths to which it is compared, e.g. the length sent to the comparator 131 via the signal conductor 135, which is indicative of e.g. a fast heart rate on the verge of hemodynamic instability when the time interval is simultaneously short. The third situation occurs when the current arc length is longer than two of the arc lengths to which it is compared, e.g. so comparator 130 and comparator 131 produce output signal 1 . This could e.g. correspond to a normal, stable heart rate between e.g. 80-120 pulses/minute. The fourth situation occurs when the current arc length is longer than three of the arc lengths to which it is compared, e.g. so comparator 129, comparator 130 and comparator 131 all produce output signal 1 . This may correspond to a slow rate on the verge of stability when the time interval is simultaneously long. Finally, the fifth situation occurs when the arc length is longer than all the other arc lengths to which it is compared, i.e. all the comparators 128, 129, 130, 131 produce output signal 1 . When the time interval is simultaneously long, this is indicative of bradycardia in a heart whose pumping capacity is greatly diminished, i.e. a hemodynamically unstable heart. So the control device 111 can, on the basis of the signals from the comparators 128, 129, 130, 131 , determine whether or not the heart is stable.

It can be noted that the derivative of the signal need not be established explicitly but can be estimated by sampling the signal values and having the difference between two sampled value correspond to the derivative. With an adequate sampling frequency and relatively "well-behaved" curves, the estimated value for the derivative will suffice for analysis.

FIG. 14 shows a unipolar single chamber pacemaker 140 connected to a heart 141. A tip electrode 142 is placed in the right ventricle of the heart 141 and connected, via an electrode conductor 143 , to a pulse generator 144 . A stimulation pulse from the pulse generator 144 is fed to the heart via the electrode conductor 143 and the tip electrode 142 and is returned to the heart 141 through body tissue, the pacemaker can 145 and back to the pulse generator 144 . An impedance meter 146 , also connected to the pacemaker can 145, is also connected to the electrode conductor 143 for measuring impedance across the chest, the impedance of the heart extractable therefrom through filtration.

The measured impedance is sent to a signal conditioning unit 147 in which the signal is amplified, filtered, buffered and derived in the same way as previously described, and digitized. The digitized signals are transferred to a sequential RAM 148 and then to an analyzer 149 whose function is described in greater detail below in conjunction with FIG. 16. A control device 150 controls the pulse generator 144 and the impedance meter 146.

Via a telemetry unit 151 , using a programming unit 152 , a physician can communicate with the

pacemaker 140 .

An impedance signal 161 is shown in FIG. 15 with an ECG tracing 160 to illustrate the way in which impedance varies during a heart cycle.

In FIG. 16, the impedance signal and its derived signal have been plotted in a coordinate system with impedance Z as one axis and the derivative dZ/dt as the other axis. The plotted impedance signal and impedance derivative signal 162 form a simple, closed curve for each heart cycle. The zero impedance level has been placed at the lowest value of the impedance signal 161 . The upper part of the derivative axis, i.e. the positive derivative, corresponds to systole, i.e. the contraction phase of the heart cycle, and the negative derivative corresponds to diastole, i.e. the blood filling phase. In principle, it is this impedance signal and impedance derivative signal 162 which are stored in the RAM 148 in FIG. 14.

The impedance signal and impedance derivative signal 162 are used by the analyzer 149 for monitoring and controlling the emission of stimulation pulses to the heart. Here, there are different types of threshold values the analyzer can sense in establishing the time for emission of a stimulation pulse. For example, a threshold value 163 can be set for the impedance, whereby a stimulation pulse is emitted when the impedance signal exceeds the threshold value 163 during diastole. Another way is to set the threshold value at a particular derivative value 164 which the negative derivative must exceed during its ascent at the end of diastole. Alternately, both conditions can be used, i.e. the vector (Z, dZ/dt) is determined and a stimulation pulse emitted when the vector is shorter than a given value.

Another way of controlling the emission of stimulation pulses is based on optimization of the area covered by the impedance and impedance derivative signal 162 in each heart cycle. This can e.g. be accomplished by maximizing

$$|Z_{max} - Z_{min}| \cdot |[dZ/dt]_{max} - [dZ/dt]_{min}|$$

FIG. 17 shows an additional embodiment of the invention in the form of a pacemaker 170 connected to a heart 171 . Like previously described dual-chamber pacemakers, this pacemaker is also connected to the heart by a first tip electrode 172 and a first ring electrode 173 which, via a first electrode conductor 174 and a second electrode conductor 175 , is connected to an atrial pulse generator 176 . An atrial detector 177 is connected in parallel across the atrial pulse generator 176 . The atrial detector 177 can e.g. sense ECG signals or sense the impedance between the first tip electrode 172 and th first ring electrode 173 .

A second tip electrode 178 and a second ring electrode 179 are placed in the ventricle of the heart 171 and connected, via a third electrode conductor 180 and a fourth electrode conductor 181 , to a ventricular pulse generator 182 in the pacemaker 170 . A ventricular detector 183 is connected in parallel across the ventricular pulse generator 182 .

In this embodiment, a pressure sensor 184 has also been introduced into the ventricle to sense ventricular blood pressure. The pressure sensor 184 is connected, via a signal conductor 185 , to a pressure detector 186 . The measurement values sensed by the detectors 177, 183, 186 are sent to a signal analysis device 187 for conditioning and evaluation. A control device 188 communicates with the signal analysis device 187 and also controls the pulse generators 176, 182 and the detectors 177, 183, 186 . Via a telemetry unit, a physician can retrieve and program information to/from the pacemaker 170 with a programming unit 190 .

When e.g. impedance is measured in addition to pressure, an impedance-pressure curve 195 is obtained, as shown in FIG. 18 in the impedance-pressure coordinate system drawn there. Here, the zero level for the impedance part of the curve 195 is placed on a different level than the impedance signal in FIG. 16. The closed, simple impedance-pressure curve 195 corresponds to one heart cycle. Impedance is generally unchanged at the end of diastole, whereas pressure rises because the ventricle is incapable of admitting more blood. During systole, initial pressure rapidly increases until the valves between the heart and the vascular system open, pressure is then kept largely constant while impedance increases because of the expulsion of blood. Peak pressure occurs during systole at the same time as impedance rises to a peak. Since heart muscle generally relaxes at the end of systole and blood again flows into the heart, pressure rapidly drops while impedance begins falling again.

By maximizing the area enclosed by the impedance-pressure curve 195 , the pacemaker can be controlled in the same way as the pacemaker in FIG. 14. The impedance-pressure signal 195 can also be used for detecting or verifying a tachyarrhythmia or fibrillation, since the heart's pumping capacity virtually disappears then, even if the ECG signal can still look normal. The impedance-pressure signal 195 is then compressed, virtually into a line parallel to the impedance axis Z , on the pressure axis. The impedance-pressure signal 195 can also be used for determining the duration of different periods in the heart signal, e.g. the heart's isovolumetric relaxation phase or the heart's isovolumetric contraction phase. The latter corresponds to the preejection period (PEP) used as a parameter in the rate control of pacemakers. Ejec-

tion time can also be determined for the right ventricle (RVET) which can form a quotient with PEP for demonstrating heart insufficiency.

A noise filter, described in FIG. 19 and based on the pacemaker in FIG. 17, can also be devised with e.g. the ECG signal as an input signal to a first amplifier 200 , said signal first filtered in a first filter 201 and then fed to a first buffer 202 and to a first derivator 203 . The buffered signal and the derived signal pass a first A/D converter 204 and a second A/D converter 205 respectively and are then sent to a RAM 206. The pressure signal is simultaneously used as an input signal for a second amplifier 207 , passes a second filter 208 and is then sent to a second buffer 209 and a second derivator 210. After passing a third A/D converter 211 and a fourth A/D converter 212 respectively, these values are also fed to the RAM 206. All four related values are then sent to a comparator unit 213 in which they are compared to previously stored sequences. Since the two input signals have different origins, one electrical and one mechanical heart variable, they are affected by different kinds of noise. When the signals are subjected to parallel comparison in this way, noise can be identified when one signal is affected but not the other. Different noises can be separated and sent to a correction unit 214 to which the related values are also sent from the RAM 206 for correction. Corrected values are sent to a second RAM 215 for subsequent analysis e.g. in one of the abovedescribed ways.

Another kind of filter which can be obtained in accordance with the present invention is shown in FIG. 20. As before, the input signal is fed to an amplifier 220 and a filter 221 before being transferred to a buffer 222 and to a derivator 223 . The signals are digitized in a first A/D converter 224 and a second A/D converter 225 respectively before being fed to a floating averager 226 which over a given period of time calculates the average value for the curve formed by the two signals. The average values are then sent to a sequential RAM 227 for additional signal conditioning. This filtration can also be performed on two separately received measurement signals.

FIG. 21 shows a three-dimensional coordinate system with an impedance axis Z , a pressure axis P and an ECG axis ECG. The signals can be supplied by e.g. the pacemaker 170 in FIG. 17. The impedance-pressure-ECG curve 230 obtained can then be analyzed to control a pacemaker or in the diagnosis of heart diseases or other anomalies in the heart. Certain characteristic parts of the impedance-pressure-ECG signal are easy to recognize, such as the P wave 231 , the QRS complex 232 and the T wave 233 . In principle, the impedance-pressur curve 195 in FIG. 18 corresponds to a projection of the impedance-pressure-ECG curve 230 in the impedance-pressure plane Z-P, and any reduction in sam along the pressure axis indicates that the heart in question is no longer pumping any blood, even if the ECG signal may in itself be virtually unchanged. Different areas (or volumes) can be entered into this coordinate system Z-P-ECG . The analysis can then be performed so the areas passed by the curve and the sequence in which the areas are passed are recorded and compared to previously recorded sequences.

FIG. 22 shows another version of the way the invention creates an opportunity for effective analysis of signals originating in the heart. A pacemaker 240 is connected to a heart 241 , as previously described, with a tip electrode 242 and a ring electrode 243 connected, via a first electrode conductor 244 and a second electrode conductor 245 , to a pulse generator 246 . A detector 247 is connected in parallel across the pulse generator 246 . A pressure sensor 248 is also placed in the ventricle of the heart 241 and transfers signals, via a first signal conductor 249 , to a pressure detector 250 . An acoustic sensor 251 senses heart sounds, e.g. valve noise, and transfers them, via a signal conductor 252 to an acoustic detector 253. The measurement signals picked up by the detectors 247, 250, 253 are transferred to a signal analysis device 254 for analysis. The signal analysis device communicates with a control device 255 which, in turn, controls the pulse generator 246 and the detectors 247, 250, 253 .

Via a telemetry unit 256, as previously described, a physician can exchange information with the pacemaker via a programming unit 257 .

In this instance, the recorded heart sounds are used as subconditions for the signal analysis to which impedance and pressure signals are subjected. In e.g. area analysis of the signal, one condition could be that the impedance-pressure curve should be in a particular area at the second heart sound for function to be regarded as normal. Heart sounds can also be used to start or stop timings.

In the above embodiments, the analysis of heart function with ECG, impedance, pressure and heart sounds has been described in conjunction with an ECG apparatus and different kinds of implantable pacemakers. Combining the described embodiments in different ways and even using other heart signals, such as blood flow and heart wall movements, is naturally fully possible. The invention can further be implemented in other devices such as cardioverters, defibrillators and implantable heart detectors.

Claims

1. A device (2; 40; 80; 100; 140; 170; 240) for analyzing the function of a heart, comprising a measurement unit (47, 53; 109; 146; 177, 182, 183; 250, 253) for generating a first measurement signal related to a first electrical or mechanical heart variable, and an evaluation unit (6; 54; 88; 110; 149; 187; 254) for evaluating the measurement signal, characterized in that the device further comprises a means (13; 55; 84; 123; 147; 187; 254) for generating a parameter signal related to a heart variable, and the evaluation unit (6; 54; 88; 110; 149; 187; 254) analyzes related values for the measurement signal and parameter signal.

2. A device as claimed in claim 1, wherein the evaluation unit plots the first measurement signal against the parameter signal and analyzes the morphology and/or chronological course of the obtained curve.

3. A device as claimed in claim 1 or 2, wherein the means for generating a parameter signal comprises a derivator which derives the measurement signal, the derived measurement signal then serving as the parameter signal.

4. A device as claimed in claim 1 or 2, wherein the means for generating a parameter signal senses a second heart variable and generates a second measurement signal serving as the parameter signal.

5. A device as claimed in any of the above claims, wherein a further measurement unit generates at least one further measurement signal related to at least one further heart variable, whereby the evaluation unit analyzes related values for the first measurement signal, the parameter signal and the further measurement signal.

6. A device as claimed in any of the above claims, wherein a comparator unit (18) continuously senses the related values in order to detect signal drift by the related values, and a compensation unit (21) compensates the current related values for any current signal drift.

7. A device as claimed in any of the above claims in combination with claim 4, wherein a filter unit (213, 214) compares changes in the respectivly related values to previously stored related values, and noise is identified if a noise change is found in one related value without any equivalent change being found in the second related value, and the noisy related value is compensated for the specific noise.

8. A device as claimed in any of the above claims, wherein a floating averager (226) continuously calculates the average value for the respective related value over a predetermined previous period of time.

9. A device as claimed in any of the claims 3 to 5 in combination with claim 2, wherein the evaluation unit comprises an arc length calculator which calculates the arc length of the curve, preferably for one heart cycle, the calculated arc length value then designating the condition of the heart's function.

10. A device as claimed in claim 9, wherein the measurement unit (109) measures impedance in the heart, the means for generating a parameter signal (123) derives the impedance signal, an A/D converter (125) digitizes the impedance signal and the impedance derivative signal, the arc length calculator (127) calculates the arc length for each heart cycle of the curve to which the impedance signal and the impedance derivative signal correspond, a number of comparators (128, 129, 130, 131) respectively compares the calculated arc length to a predetermined arc length, the respective comparator (128, 129, 130, 131) then generating an output signal if the calculated arc length exceeds the respective predetermined arc length, and a microprocessor (111), using the output signals from the comparators, determines whether or not the heart is hemodynamically stable.

11. A device as claimed in any of the claims 3 to 5 in combination with claim 2, wherein the evaluation unit comprises an area calculator which calculates an area, largely enclosed by the curve, for every heart cycle, the calculated area then designating the condition of the heart's function.

12. A device as claimed in any of the claims 3 to 5 in combination with claim 2, wherein the evaluation unit plots an essentially simple, closed curve, and a distance calculator calculates the distance between specific points on the curve, preferably between maximum and minimum points, the calculated distances designating the condition of the heart's function.

13. A device as claimed in claim 2 or in any of the claims 3 to 5 in combination with claim 2, wherein the evaluation unit comprises a mem-

ory for storing the obtained curve for each heart cycle and a comparator for comparing the obtained curve with at least one predetermined curve, the predetermined curve being either a previously stored curve or a programmed curve.

14. A device as claimed in any of the claims 1 to 5, wherein the evaluation unit comprises a memory for storing the course of related values, and a comparator compares the stored course with at least one predetermined course, the predetermined course being either a previously stored course or a programmed course.

15. A device as claimed in claim 14, wherein the device comprises a component for identifying a sequence in which the course of related values passes a predetermined number of areas, the comparator comparing the sequence with a predetermined sequence, the predetermined sequence being either a previously identified sequence or a programmed sequence.

FIG 1

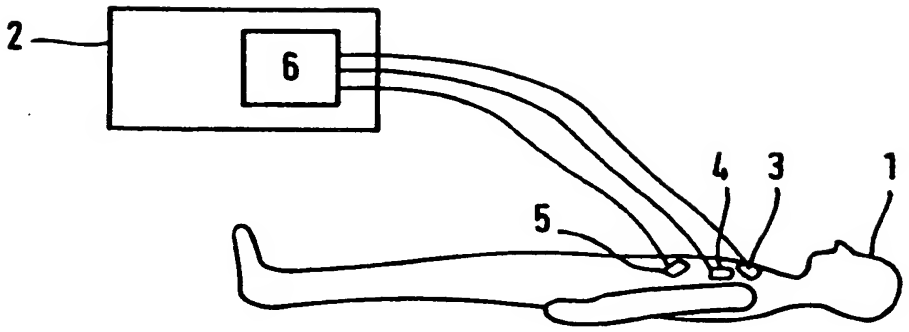


FIG 2

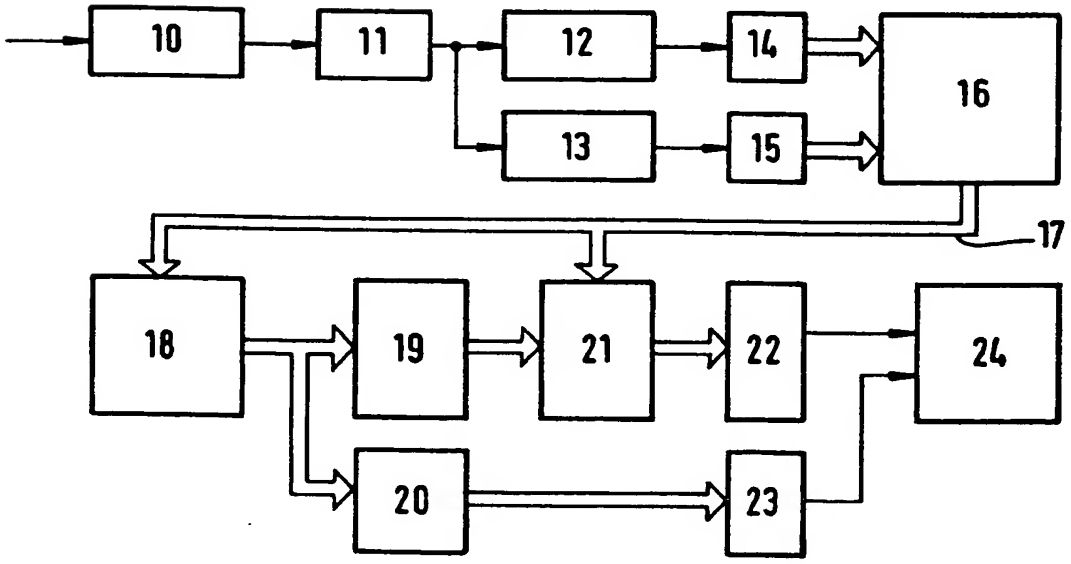


FIG 3

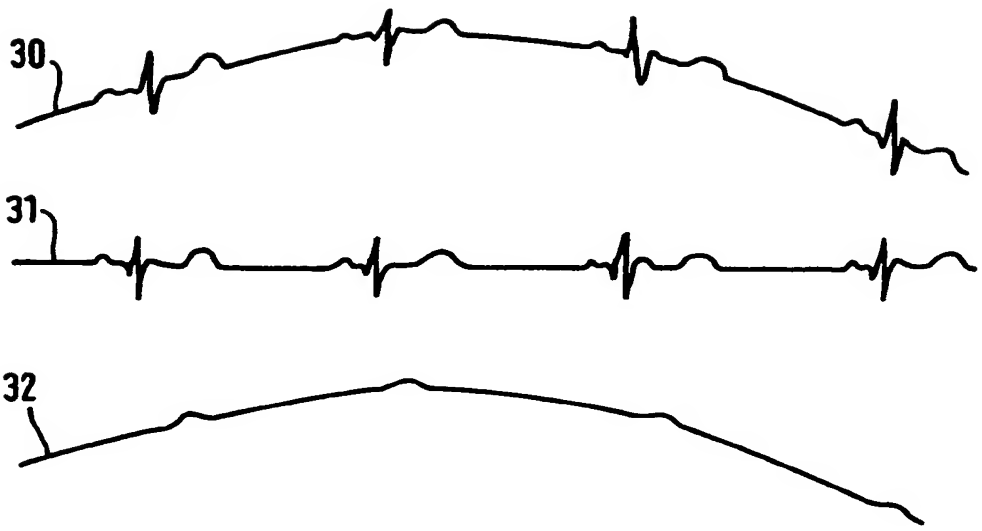
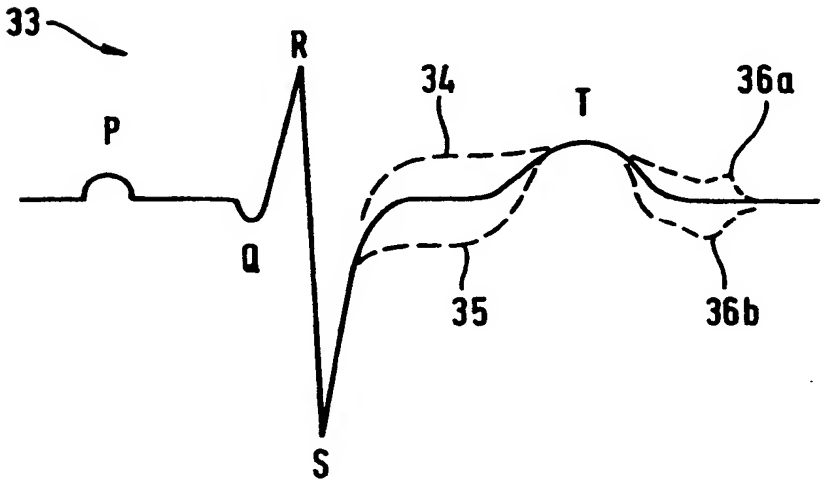


FIG 4



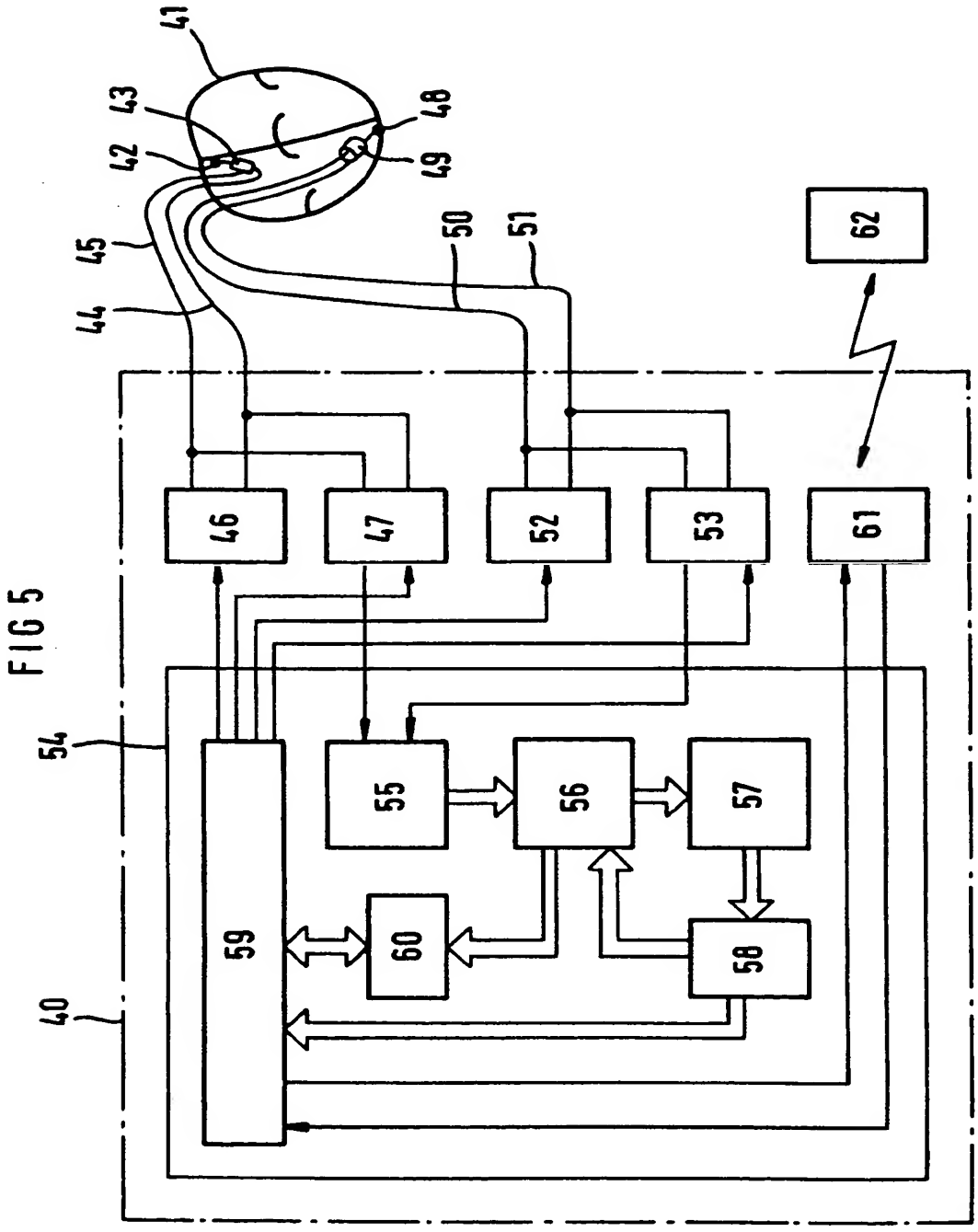


FIG 5

FIG 6

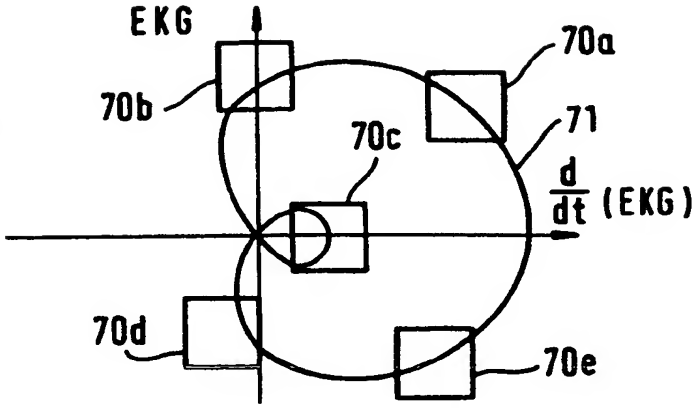


FIG 7

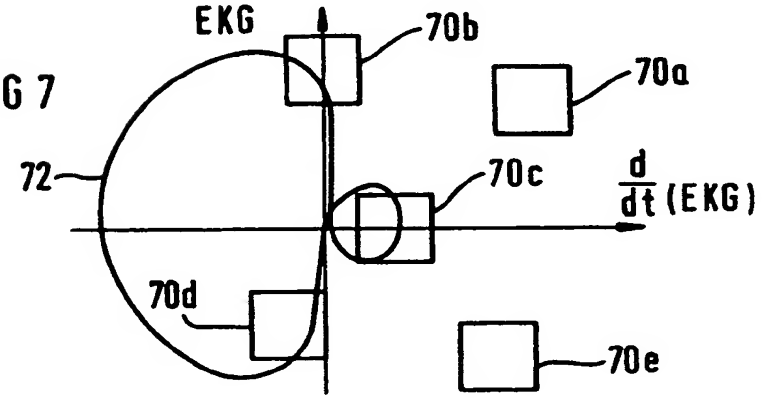
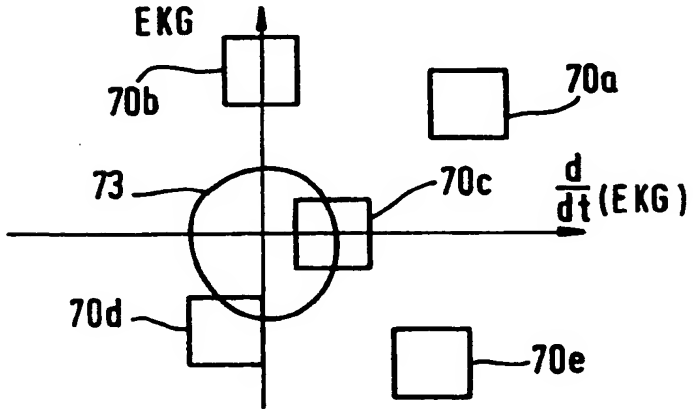


FIG 8



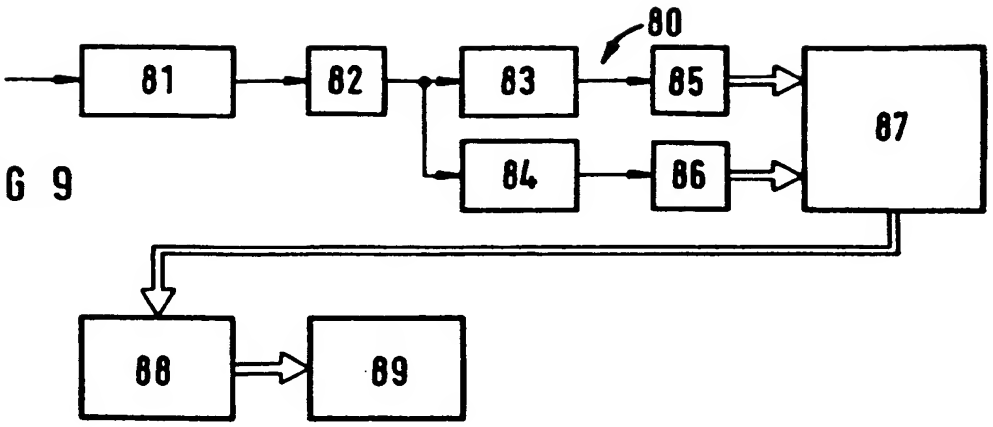


FIG 9

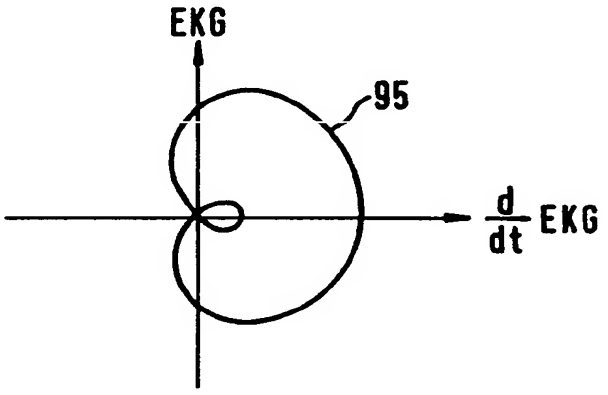


FIG 10

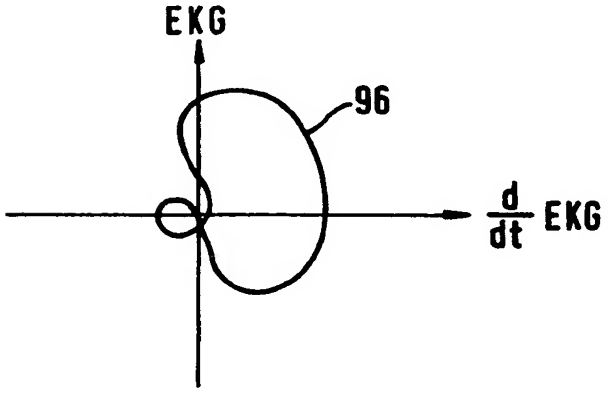


FIG 11

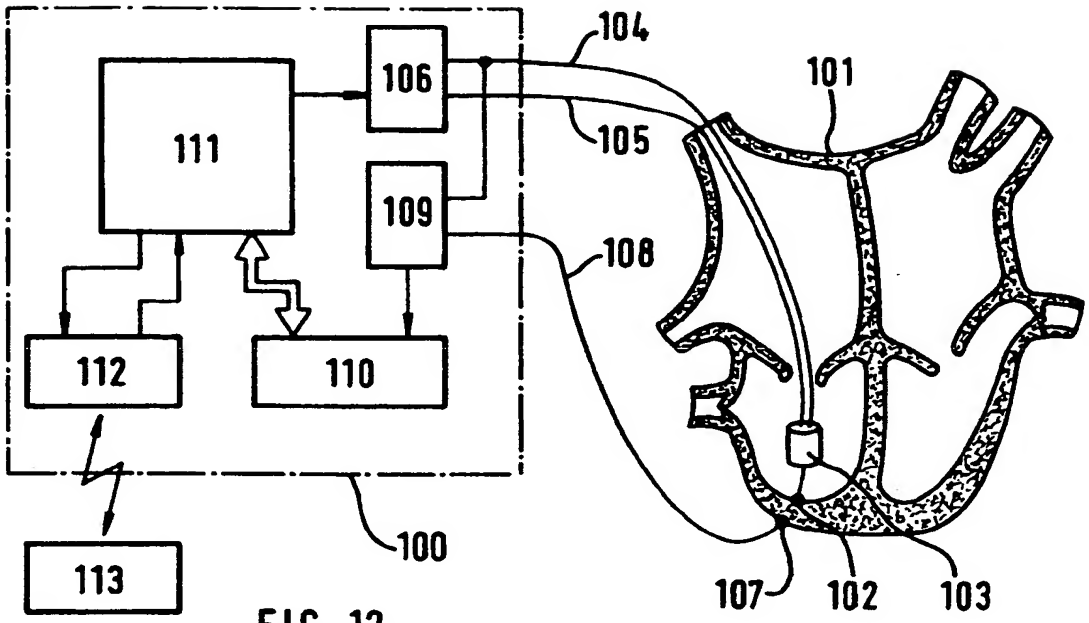

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FIG 12

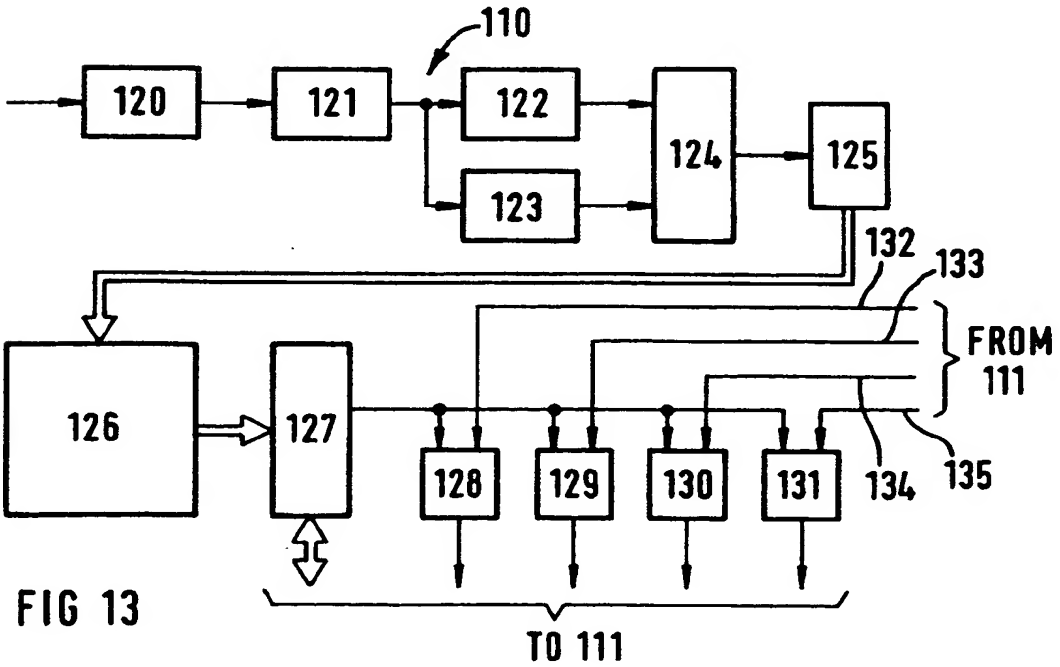
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FIG 13

FIG 14

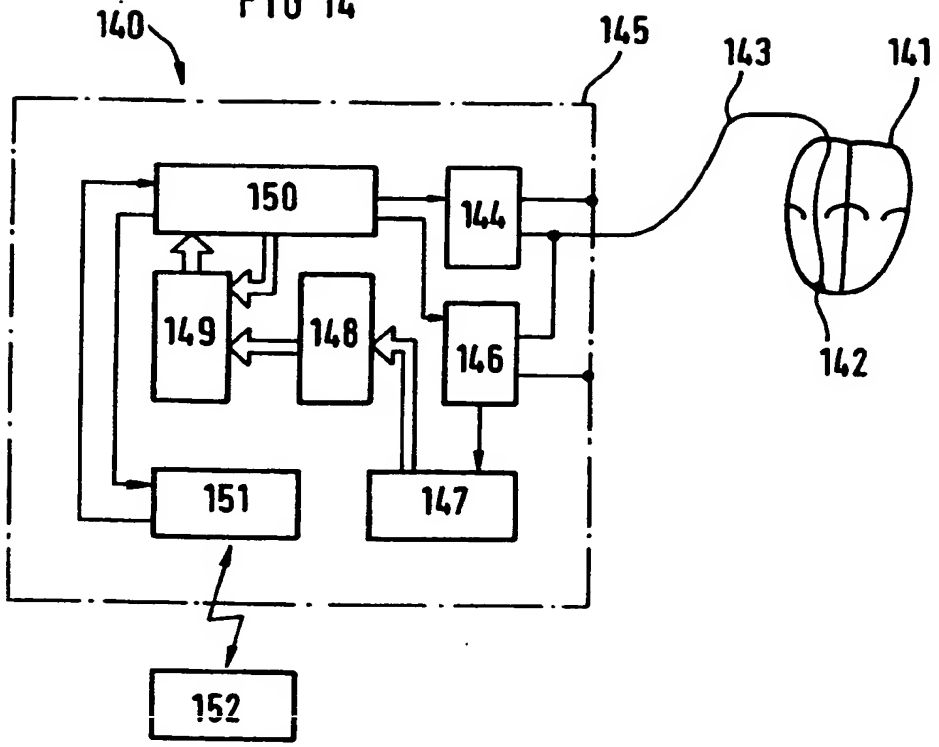
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FIG 15

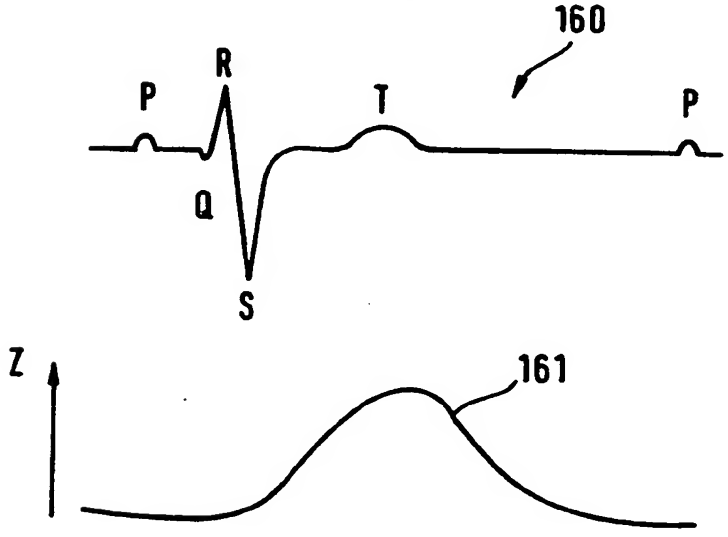
160
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FIG 16

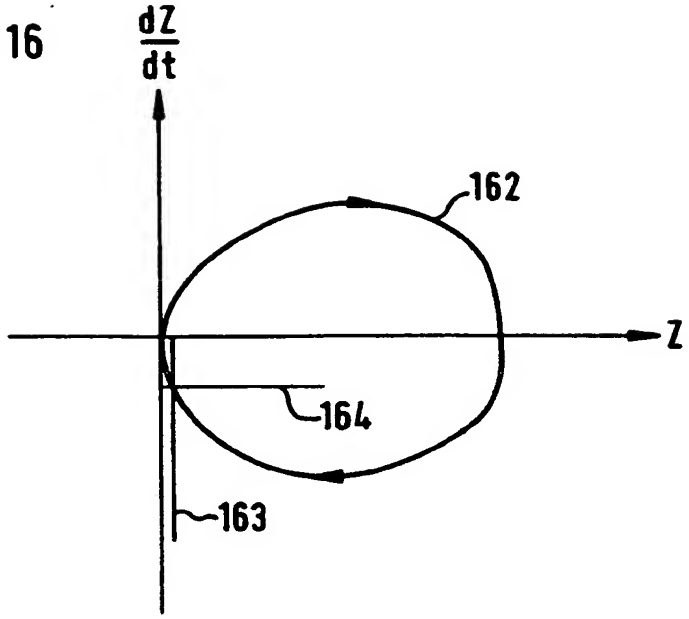
dZ/dt
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FIG 17

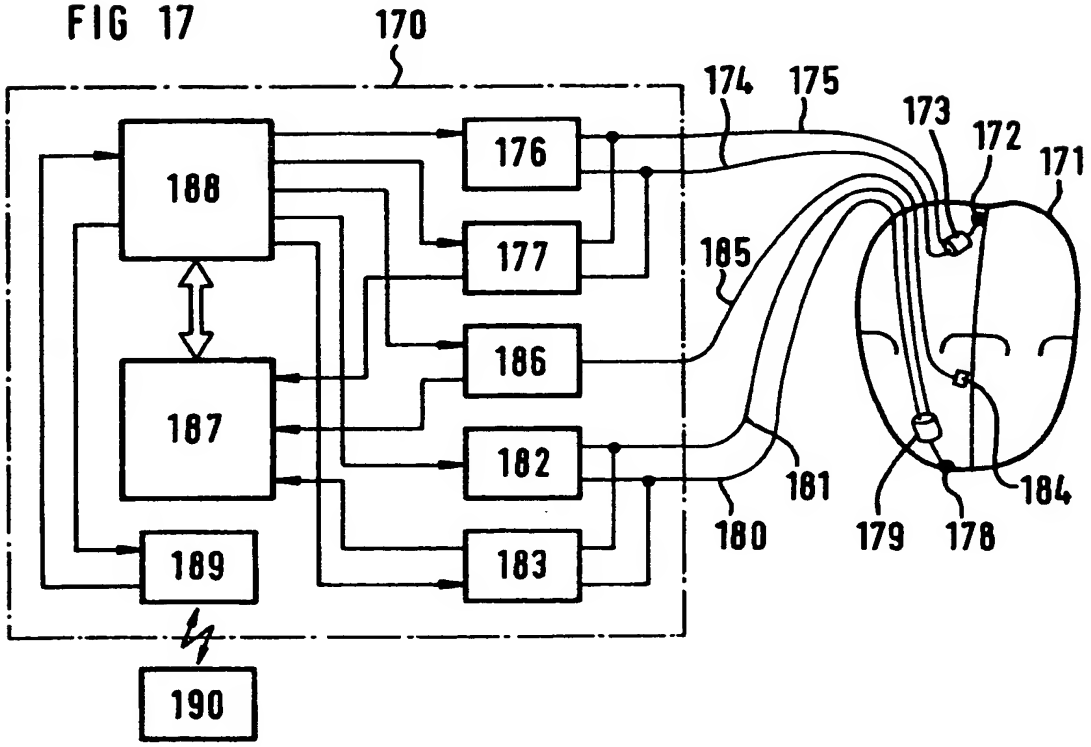
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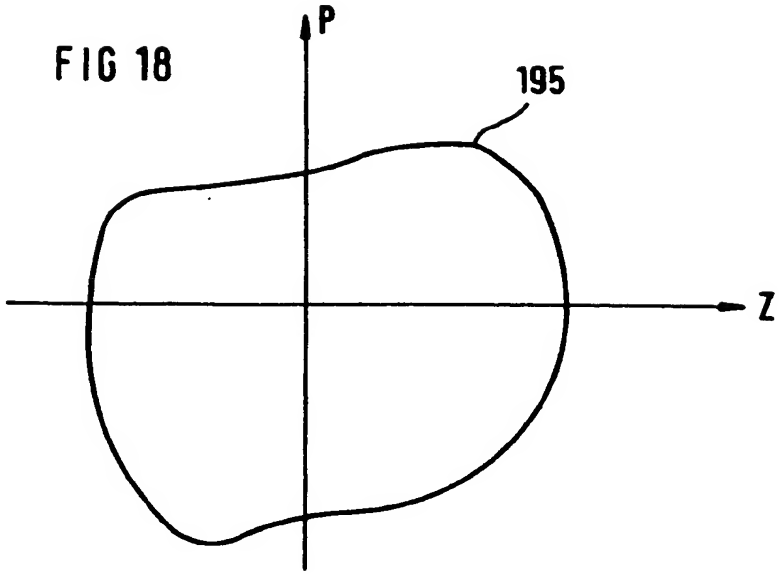
FIG 18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Z

FIG 19

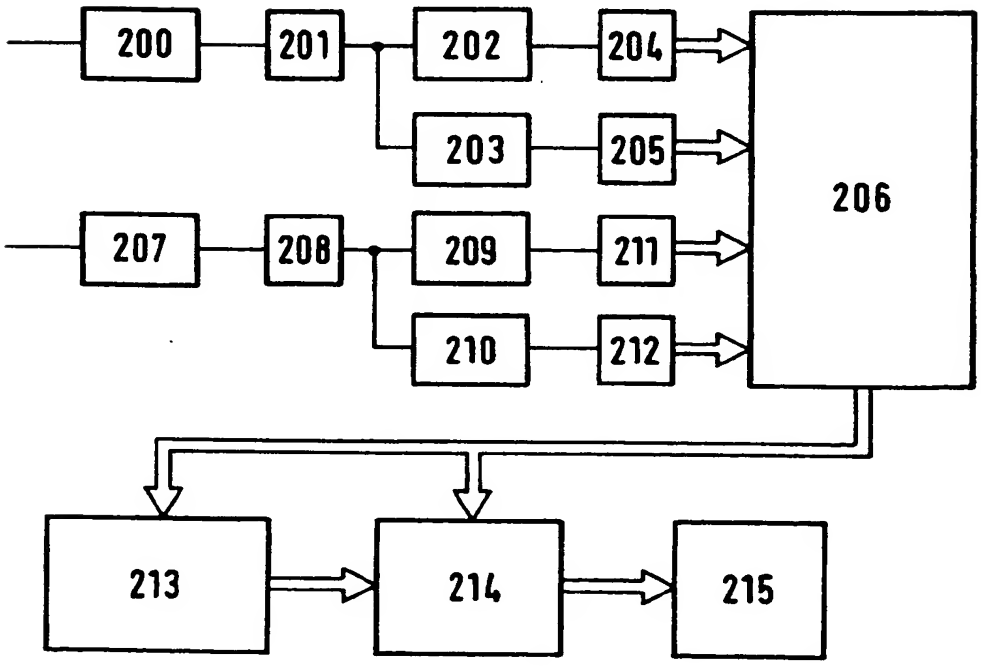
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FIG 20

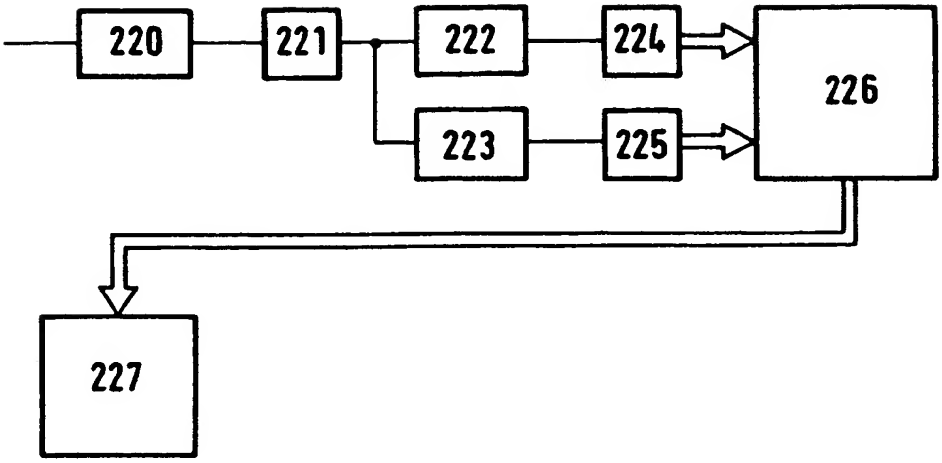


FIG 21

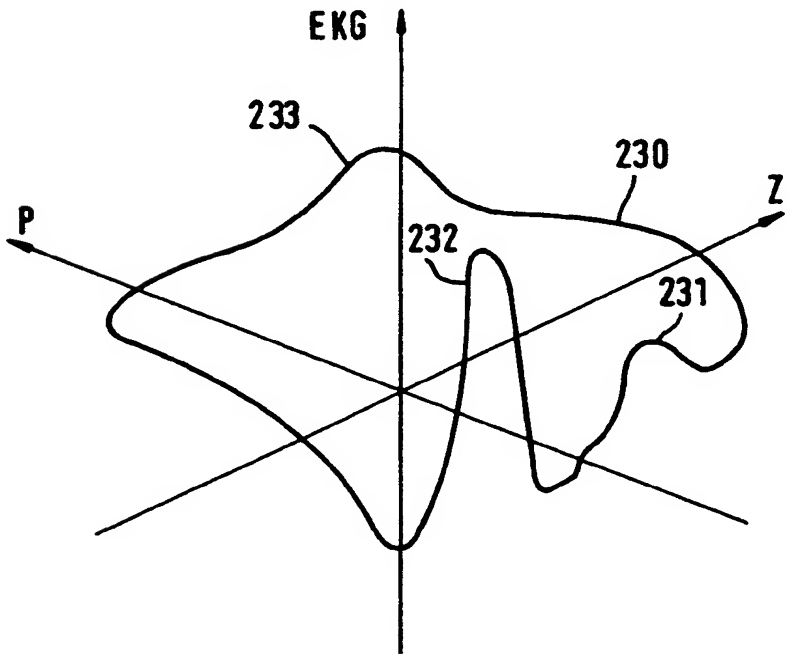
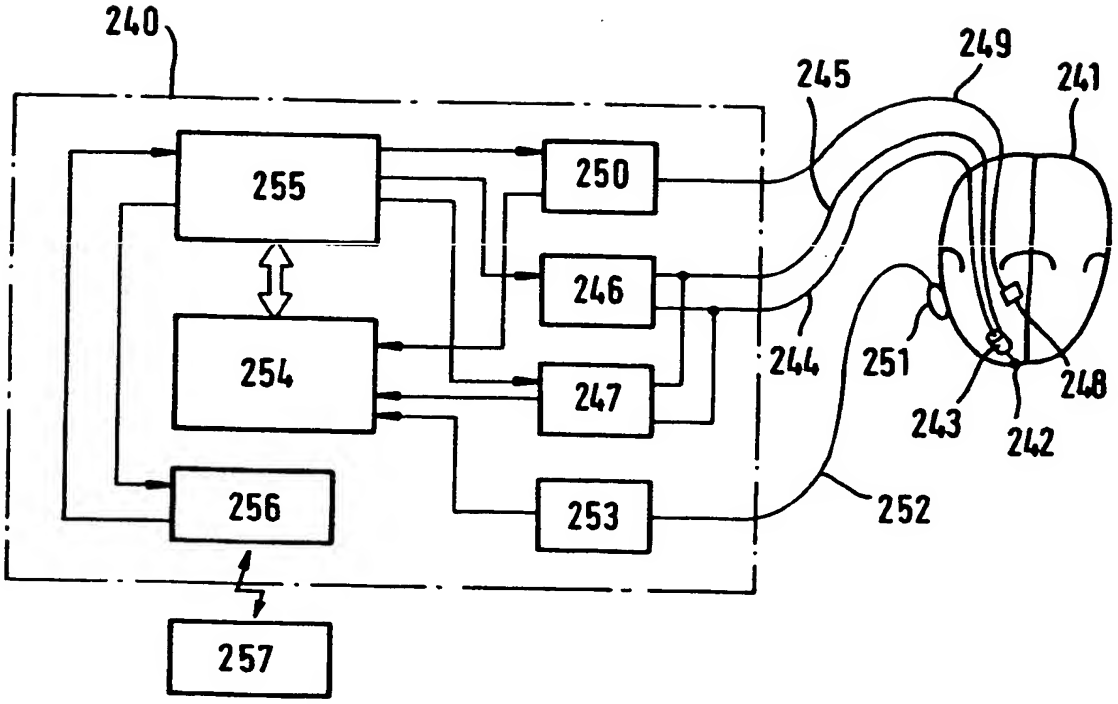


FIG 22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